

### Remarks

Claims 121-127 and 129-131 are pending in this application and are rejected on various grounds. Solely to expedite prosecution in this case, claims 121-123 have been amended to recite "wherein said polypeptide induces chondrocyte redifferentiation," support for which is found in the instant specification at least on page 530, Example 159. The rejections to the presently pending claims are respectfully traversed.

### Priority

Applicants submit that they rely on the "chondrocyte redifferentiation assay" for patentable utility of this case which was first disclosed in International Application PCT/US00/08439, filed March 30, 2000, priority to which has been claimed in this application. Based on the disclosure of SEQ ID NO: 119, Figure 70, PRO943 in Application PCT/US00/08439, Applicants believe that the application provides adequate support and that meets the requirements of 35 USC § 101 and 112, first paragraph. Hence, Applicants should be entitled to at least an effective filing date of **March 30, 2000**.

### Claim Rejections – 35 USC 112, first paragraph - enablement

Claims 121-123 are rejected under 35 U.S.C. §112, first paragraph allegedly because "the specification, while is enabling for a full length PRO943 protein of SEQ ID NO: 119, does not reasonably provide enablement for a polypeptide at least 90-99% identical to SEQ ID NO: 119. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims". For the reasons outlined below, Applicants respectfully disagree.

As discussed under the section on "priority", Applicants rely on the chondrocyte redifferentiation assay for patentable utility for the PRO943 protein. This is a well-established assay and the pending claims concern polypeptides having 90%, 95% or 99% sequence identity with the disclosed polypeptide sequence SEQ ID NO: 119 that induce chondrocyte redifferentiation. Based on the detailed description of the cloning and expression of variants of PRO943 in the specification, the description of the chondrocyte redifferentiation assay and knowledge of one skilled in the art, Applicants submit that at the time the invention was made one of ordinary skill in the art would have known how to prepare variants 90-99% identical to

SEQ ID NO: 119, since making mutants was routine in the art. The positions at which the mutations occur are irrelevant, so long as the mutants obtained test positive in the chondrocyte redifferentiation assay. Such variants can be identified in assays that were well known in the art at the relevant time, without undue experimentation. Thus, the invention as currently claimed is fully enabled, and Applicants request that the present 35 U.S.C. §112, first paragraph rejections to the pending claims be withdrawn.

### **Claim Rejections – 35 USC § 112, first paragraph- written description**

Claims 119-123, 130 and 131 are rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. The Examiner asserts that the claims are drawn to polypeptides at least 80-99% identical to SEQ ID NO:119 and thus are genus claims. The Examiner further asserts that the specification does not indicate what distinguishing attributes are shared by the member of the genus. Applicants respectfully traverse this rejection as it applies to the pending claims.

### **The Legal standard for Written Description**

The well- established test for sufficiency of support under the written description requirement of 35 U.S.C. §112, first paragraph is whether the disclosure "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *In re Kaslow*, 707 F.2d 1366, 1375, 212 USPQ 1089, 1096 (Fed. Cir. 1983); see also *Vas-Cath, Inc. v. Mahurkar*, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis. see e.g. *Vas-Cath, Inc. v. Mahurkar*, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The factual determination in a written description analysis depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. *Union Oil v. Atlantic Richfield Co.*, 208 F. 3d 989, 996 (Fed. Cir. 2000).

### **Arguments**

The instant invention, as currently claimed, is directed to polypeptides having 90%, 95% or 99% sequence identity with the disclosed polypeptide sequence SEQ ID NO: 119 which share the ability to induce chondrocyte redifferentiation. Thus, the pending claims are now drawn to a

genus of polypeptides defined by both structural and functional features, and only those variants that test positive in the chondrocyte redifferentiation assay are encompassed by these claims.

The present invention pertains to the field of recombinant DNA/protein technology. It is well established that the level of skill in this field is very high since a representative person of ordinary skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of such highly skilled artisan as of the date the invention was made. In view of Applicant's possession of the PRO943 sequence (SEQ ID NO: 119), and the requirement in the claims that the claimed polypeptides have the ability to induce chondrocyte proliferation, one skilled in the art at the effective filing date of this application would have reasonably concluded that Applicants were in the possession of the invention currently claimed. Indeed, according to well established case law, such as *The Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), the written description requirement for a genus can be met by disclosing a representative number of species within the genus coupled with functional characteristics unifying the genus. The combination of structural and functional features recited in the claims as currently amended, sufficiently describes the invention claimed such that at the effective filing date one skilled in the art could practice the invention within the full scope of the pending claims without undue experimentation. The combination of structural and functional features recited in the claims as currently amended, meets this legal standard.

Hence, Applicants request that the present rejection to the present claims be reconsidered and withdrawn.

#### **Claim Rejections – 35 USC § 112, first paragraph- enablement**

Claims 121-127, 129-131 are rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

Applicants have amended the specification to provide the necessary assurances and therefore the current invention is enabled. Accordingly, this rejection should be withdrawn.

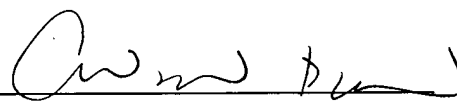
The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-2730P1C7).

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: January 5, 2004

  
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